

In re application of:

Cynthia B. Robinson, *et al.*

Application Serial No. 10/698,078

Filed: October 29, 2003

For: **COMBINATION OF
DEHYDROEPIANDROSTERONE OR
DEHYDROEPIANDROSTERONE-
SULFATE WITH A BETA-AGONIST
BRONCHODILATOR FOR
TREATMENT OF ASTHMA OR
CHRONIC OBSTRUCTIVE
PULMONARY DISEASE**

Art Unit: 1624

Examiner: Not Yet Assigned

Confirmation No.: 9187

Attorney's Docket No:
02486.0065.NPUS01

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required, or
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or
 - ☐ c. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).

- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i), and
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed _____, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is

respectfully requested to consider the cited application and the art cited therein during examination.

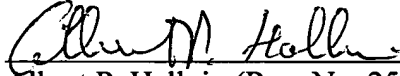
- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 02486.0065.NPUS01.

Respectfully submitted,

Date: March 26, 2004


Albert P. Halluin (Reg. No. 25,227)
Robin C. Chiang (Reg. No. 46,619)

HOWREY SIMON ARNOLD & WHITE, LLP
301 Ravenswood Avenue
Box 34
Menlo Park, CA 94025
(650) 463-8109

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

PTO FORM 1449

ATTY. DOCKET NO.

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1624

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	1.	3,994,974	Nov. 1976	Murakami et al				
	2.	4,393,066	Jul. 1983	Garrett et al.				
	3.	4,499,064	Feb. 1985	Shive				
	4.	4,575,498	Mar. 1986	Holmes et al.				
	5.	4,600,710	Jul. 1986	Liang et al.				
	6.	4,628,052	Dec. 1986	Peat				
	7.	4,894,219	Jan. 1990	Baker et al.				
	8.	4,920,115	Apr. 1990	Nestler et al.				
	9.	4,931,441	Jun. 1990	Lawrence				
	10.	4,985,443	Jan. 1991	Montes				
	11.	4,992,474	Feb. 1991	Skidmore et al.				
	12.	5,021,417	Jun. 1991	Prost				
	13.	5,059,595	Oct. 1991	Le Grazie				
	14.	5,077,284	Dec. 1991	Loria et al.				
	15.	5,108,363	Apr. 1992	Tuttle et al.				
	16.	5,110,810	May 1992	Eich et al.				
	17.	5,118,505	Jun. 1992	Költringer				
	18.	5,126,375	Jun. 1992	Skidmore et al.				
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	20.	5,173,488	Dec. 1992	Haeger				
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	22.	5,225,445	Jul. 1993	Skidmore et al.				
	23.	5,234,404	Aug. 1993	Tuttle et al.				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i> PTO FORM 1449	ATTY. DOCKET NO. 02486.0065.NPUS01	APPLICATION NO. 10/698,078
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	24.	5,258,385	Nov. 1993	Dodd et al.				
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	26.	5,270,305	Dec. 1993	Palmer				
	27.	5,286,252	Feb. 1994	Tuttle et al.				
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	29.	5,407,684	Apr. 1995	Loria et al.				
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	32.	5,489,581	Feb. 1996	Daynes et al.				
	33.	5,527,789	Jun. 1996	Nyce				
	34.	5,532,230	Jul. 1996	Daynes et al.				
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	39.	5,684,199	Nov. 1997	Francotte				
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	49.	6,156,503	Dec. 2000	Drazen et al.				

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	51.	6,441,181	Aug. 2002	Scott				
	52.	6,488,027	Dec. 2002	Moulin				
	53.	2002/0042401	Apr. 2002	Ferguson et al.				
	54.	2003/0013772	Jan. 2003	Murphy et al.				
	55.	2003/0138434	Jul. 2003	Campbell et al.				
	56.	2003/0139331	Jul. 2003	Martin et al.				
	57.	2003/0216329 A1	Nov. 2003	Robinson et al.				
FOREIGN PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	58. X	WO 93/16704		PCT				
	59. X	WO 96/16680		PCT				
	60. X	WO 97/48367		PCT				
	61. X	WO 98/03180		PCT				
	62. X	WO 00/54763		PCT				
	63. X	WO 01/015745		PCT				
	64. f	WO 02/069955		PCT				
	65. f	WO 02/85296		PCT				
	66. f	WO 03/072572		PCT				
	67. X	WO 04/014293 A2		PCT				

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<p align="center">OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)</p>		
68.	<input checked="" type="checkbox"/>	Araneo <i>et al.</i> , "Dehydroepiandrosterone Reduces Progressive Dermal Ischemia Caused by Thermal Injury", <i>J. Surg. Res.</i> 59(2):250-62 (1995).
69.	<input checked="" type="checkbox"/>	Bonnett <i>et al.</i> , "Dehydroepiandrosterone (DHEA) prevents and reverses chronic hypoxic pulmonary hypertension," <i>PNAS</i> 100(16):9488-93 (2003).
70.	<input checked="" type="checkbox"/>	Budavari, <i>The Merck Index</i> 11 th ed., 1989, pp. 660-661, monograph 4141.
71.	<input checked="" type="checkbox"/>	Coleridge <i>et al.</i> , "Intravenous aminophylline confers no benefit in acute asthma treated with intravenous steroids and inhaled bronchodilators", <i>Aust. N.Z. J. Med.</i> 23:348-54 (1993).
72.	<input checked="" type="checkbox"/>	Dashtaki <i>et al.</i> , "Dehydroepiandrosterone and Analogs Inhibit DNA Binding of AP-1 and Airway Smooth Muscle Proliferation ¹ ", <i>J. Pharmacol. Exp. Thera.</i> 285(2):876-83 (1998).
73.	<input checked="" type="checkbox"/>	Dompeling <i>et al.</i> , "Treatment with Inhaled Steroids in Asthma and Chronic Bronchitis: Long Term Compliance and Inhaler Technique", <i>Family Practice</i> 9(2):161-6 (1992).
74.	<input checked="" type="checkbox"/>	Dunn, <i>et al.</i> , "Dehydroepiandrosterone sulphate concentrations in asthmatic patients: pilot study," <i>N.Z. J. Med.</i> 97(768):805-8 (1984).
75.	<input checked="" type="checkbox"/>	Duplantier, <i>et al.</i> , Novel pharmacological approaches to the treatment of asthma: status and potential of therapeutic classes", <i>DDT</i> 1(5):199-207 (1996)
76.	<input checked="" type="checkbox"/>	Dworski <i>et al.</i> , "Conspectus: Inhaled Steroids in Asthma", <i>Comprehensive Therapy</i> , 18:3 (1992).
77.	<input checked="" type="checkbox"/>	Fehér <i>et al.</i> , "Adrenocortical Function in Bronchial Asthma", <i>Acta Medica Hungarica</i> 40(2-3):125-32 (1983).
78.	<input checked="" type="checkbox"/>	Fehér, <i>et al.</i> , "Dehydroepiandrosterone Therapy of Patients with Corticosteroid Dependent Bronchial Asthma," <i>Natl. Institute of Rheumatism and Physiotherapy, in XIII Congress of the European Academy of Allergology and Clinical Immunology</i> , eds. (Saba, <i>et al.</i> , Debrecen Hungary (1986).
79.	<input checked="" type="checkbox"/>	Hampl <i>et al.</i> , "Dehydroepiandrosterone sulphate reduces chronic hypoxic pulmonary hypertension in rats," <i>J. Eur. Respir.</i> 21:862-5 (2003).
80.	<input checked="" type="checkbox"/>	Holzmann <i>et al.</i> , "Therapy of Psoriasis with Dehydroepiandrosterone-Enanthate. II. Intramuscular Depot Application of 300 mg", <i>Arch. Dermatol. Forsch.</i> 247(1):23-8 (1973) (German with English Abstract).
81.	<input checked="" type="checkbox"/>	Hummel <i>et al.</i> , "Comparison of oral-steroid sparing by high-dose and low-dose inhaled steroid in maintenance treatment of severe asthma", <i>The Lancet</i> , 340(8834/8835):1483-7 (1992).
82.	<input checked="" type="checkbox"/>	Itagaki <i>et al.</i> , "Effect of Cortisol on the Release of Human Decidual", <i>Caplus</i> , 114875 (1991) (Japanese with English Abstract).

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83.	X	Koó <i>et al.</i> , "Our experiences with Dehydroepiandrosterone Therapy in Steroid-Dependent Intrinsic Bronchical Asthma", <i>Orvosi Hetilap</i> 128(38):1995-7 (1987) (Hungarian).
84.	X	Koó <i>et al.</i> , " Our experiences with Dehydroepiandrosterone Therapy in Steroid-Dependent Intrinsic Bronchical Asthma ", <i>Orvosi Hetilap</i> 128(38):1995-7 (1987) (English translation).
85.	+	Lejeune, "Pathogenesis of Mental Impairment in Trisomy 21", <i>Annales de Génétique</i> , 92:27643 (1996) (French with English Abstract).
86.	+	Mileva <i>et al.</i> , "Androstenedione, DHEA sulfate, cortisol, aldosterone and testosterone in bronchial asthma patients", 07608054 (1990) (Russian with English Abstract).
87.	+	Nakagawa, <i>et al.</i> , "The Properties of Water of Crystallization of Sodium Prasterone Sulfate," <i>Chem. Pharm. Bull</i> 29(5):1466-9 (1981)
88.	+	Nakagawa, <i>et al.</i> , "The Grinding and Drying on the Solid State Stability of Sodium Prasterone Sulfate," <i>Chem. Pharm. Bull</i> 30(1):242-8 (1982)
89.	X	Pashko <i>et al.</i> , "Inhibition of 7,12-dimethylbenz(a)anthracene-induced Skin Papillomas and Carcinomas by Dehydroepiandrosterone and 3-beta-methylandrost-5-en-17-one in mice", <i>Cancer Res.</i> 45(1):164-6 (1985).
90.	X	Peeters <i>et al.</i> , "Differences in Purine Metabolism in Patients with Down's Syndrome", <i>J. Intellect. Diabil. Res.</i> 37:471 (1993). Abstract.
91.	X	Reed, "Aerosol Steroids as Primary Treatment of Mild Asthma", <i>New England J. Med.</i> , 325(6):425-6 (1991).
92.	X	Rowe <i>et al.</i> , "Effectiveness of Steroid Therapy in Acute Exacerbations of Asthma: A Meta-analysis", <i>Amer. J. Emergency Med.</i> , 10(4):301-10 (1992).
93.	X	Sasaki <i>et al.</i> , "Cervical Ripening with Dehydroepiandrosterone Sulphate", <i>Br. J. Obstet. Gynaecol.</i> 89(3):195-8, (1982).
94.	X	Sciarra <i>et al.</i> , "Aerosols", Remington's Pharmaceutical Sciences, 18 th ed. (1990), Eds. Gennaro <i>et al.</i> , pp. 1873-5 and 1694-1712.
95.	X	Sharma <i>et al.</i> , "Screening of potential chemopreventive agents using biochemical markers of carcinogenesis", <i>Cancer Res.</i> 54(22):5848-55 (1994).
96.	X	Shomali, "The Use of Anti-Aging Hormones. Melatonin. Growth Hormone, Testosterone, and Dehydroepiandrosterone: Consumer Enthusiasm for Unproven Therapies", <i>Md. Med. J.</i> 46(4):181-6 (1997).
97.	X	Sonka <i>et al.</i> , "Gout and Dehydroepiandrosterone: 3. DHEA Administration", <i>Endokrynologia Polska</i> 24(3):209-18 (1973).

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	98.	Sur et al., "Double-blind trial pyroxidine (vitamin B6) in the treatment of steroid-dependent asthma", <i>Ann. Allergy</i> , 70:147-52 (1993).
	99.	Schwartz et al., "Inhibition of 7,12-dimethylbenz[a]anthracene- and urethan-induced lung tumor formation in A/J mice by long-term treatment with dehydroepiandrosterone," <i>Carcinogenesis</i> 2(12):1335-7 (1981)
	100.	Van de Graaf et al., "Respiratory Membrane Permeability and Bronchial Hyperreactivity in Patients with Stable Asthma: Effects of Therapy with Inhaled Steroids", <i>Bronchial Asthma and Respiratory Membrane Permeability</i> 143:362-8 (1991).
	101.	Van Vollenhoven et al., "Dehydroepiandrosterone in SLE. Results of a Double-Blind, Placebo-Controlled, Randomized Clinical Trial.", <i>Arthritis Rheum.</i> 38(12): 1826-31 (1995).
	102.	Wolkowitz et al., "Dehydroepiandrosterone Treatment of Depression", <i>Biol. Psychiatry</i> 41(3):311-8. (1997).

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